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In Application of

ANGEL et al.

Serial No. 09/805,239

Filed: March 14, 2001

Art Unit: 1615

Examiner: Joynes

For: SOFT CAPSULES COMPRISING POLYMERS OF VINYL ESTERS AND
POLYETHERS, THE USE AND PRODUCTION THEREOF

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AMENDMENT

Sir:

In response to the office action of March 12, 2002, kindly enter and consider the
following amendment and remarks.

08/15/2002 TBESHAH1 00000019 09805239
01 FC:116 400.00 OP

Repln. Ref: 08/15/2002 TBESHAH1 0008172700
DAH:110345 Name/Number:09805239
FC: 704 \$20.00 CR

CLEAN VERSION OF AMENDMENTS

Cancel claims 17, 25 and 26; amend claims 1-16 and 18-24; and add new claims 27-30 as follows (the following are all of the claims in the application:

131 1. (amended) A soft capsule comprising

- (a) from 10 to 100% of polymers prepared by polymerization of vinyl esters in the presence of polyethers
- (b) from 0 to 80% of structure-improving auxiliaries and
- (c) from 0 to 30 % of other constituents selected from the group consisting of fillers, release agents, flow aids, stabilizers, water-soluble or water-insoluble dyes, flavorings and sweeteners.

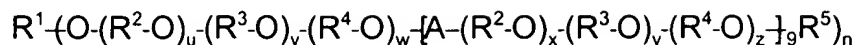
2. (amended) A soft capsule as claimed in claim 1, wherein said polymers (a) are produced by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
- b) polyether-containing compounds and
- c) from 0 to 50% of one or more copolymerizable monomers

and subsequent at least partial hydrolysis of the ester functions in the original monomers a).

3. (twice amended) A soft capsule as claimed in claim 1, wherein the polymers (a) are obtained by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
- b) polyether-containing compounds of the general formula I



in which the variables have, independently of one another, the following meaning:

R1 R¹ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-, polyalcohol residue;

R⁵ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R² to R⁴ -(CH₂)₂-, -(CH₂)₃-, -(CH₂)₄-, -CH₂-CH(R⁶)-, -CH₂-CHOR⁷-CH₂-;

R⁶ C₁-C₂₄-alkyl;

R⁷ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

A -C(=O)-O-, -C(=O)-B-C(=O)-O-, -C(=O)-NH-B-NH-C(=O)-O-;

B -(CH₂)_t-, arylene, optionally substituted;

n 1 to 1000;

s 0 to 1000;

t 1 to 12;

u 1 to 5000;

v 0 to 5000;

w 0 to 5000;

x 0 to 5000;

y 0 to 5000;

z 0 to 5000;

and

c) from 0 to 50% of one or more other copolymerizable monomers

and subsequent at least partial hydrolysis of the ester functions in the original

monomers a).

4. (twice amended) A soft capsule as claimed in claim 1, wherein the polymers (a) are

131 obtained by free-radical polymerization of

- a) at least one vinyl ester of C_1 - C_{24} -carboxylic acids in the presence of
- b) polyether-containing compounds of the general formula I with a number average molecular weight of from 300 to 100000, in which the variables have, independently of one another, the following meaning:

R^1 hydrogen, C_1 - C_{12} -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-, polyalcohol residue;

R^5 hydrogen, C_1 - C_{12} -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-;

R^2 to R^4 $-(CH_2)_2-$, $-(CH_2)_3-$, $-(CH_2)_4-$, $-CH_2-CH(R^6)-$, $-CH_2-CHOR^7-CH_2-$;

R^6 C_1 - C_{12} -alkyl;

R^7 hydrogen, C_1 - C_{12} -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-;

n 1 to 8;

s 0;

u 2 to 2000;

v 0 to 2000;

w 0 to 2000;

and

- c) one or more other copolymerizable monomers,

and subsequent at least partial hydrolysis of the ester functions in the original monomers a).

5. (twice amended) A soft capsule as claimed in claim 1, wherein the polymers (a) are obtained by free-radical polymerization of

- 31
- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
 - b) polyether-containing compounds of the general formula I with a number average molecular weight of from 500 to 50000, in which the variables have, independently of one another, the following meaning:

R¹ hydrogen, C₁-C₆-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R⁵ hydrogen, C₁-C₆-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R² to R⁴ -(CH₂)₂-, -(CH₂)₃-, -(CH₂)₄-, -CH₂-CH(R⁶)-, -CH₂-CHOR⁷-CH₂-;

R⁶ C₁-C₆-alkyl;

R⁷ hydrogen, C₁-C₆-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

n 1;

s 0;

u 5 to 1000;

v 0 to 1000;

w 0 to 1000;

and

- c) one or more other copolymerizable monomers,

and subsequent at least partial hydrolysis of the ester functions in the original monomers a).

6. (twice amended) A soft capsule as claimed in claim 1, wherein the polymers (a) are

obtained by free-radical polymerization of

- 13 1
- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
 - b) polyether-containing compounds and
 - c) one or more other copolymerizable monomers,

and subsequent at least partial hydrolysis of the ester functions in the original monomers a), wherein the polyether-containing compounds b) have been prepared by polymerization of ethylenically unsaturated alkylene oxide-containing monomers, alone or together with other copolymerizable monomers.

7. (twice amended) A soft capsule as claimed in claim 6, wherein the

polyether-containing compounds b) have been prepared by polymerization of polyalkylene oxide vinyl ethers and, alone or together with other copolymerizable monomers.

8. (twice amended) A soft capsule as claimed in claim 6, wherein the

polyether-containing compounds b) have been prepared by polymerization of polyalkylene oxide (meth)acrylates alone or together with other copolymerizable monomers.

9. (twice amended) A soft capsule as claimed in claim 2, wherein said other

copolymerizable monomers c) are selected from the group consisting of: acrylic acid, methacrylic acid, maleic acid, fumaric acid, crotonic acid, maleic anhydride and its monoesters, methyl acrylate, methyl methacrylate, ethyl acrylate, ethyl methacrylate, n-butyl acrylate, n-butyl methacrylate, t-butyl

acrylate, t-butyl methacrylate, isobutyl acrylate, isobutyl methacrylate,
2-ethylhexyl acrylate, stearyl acrylate, stearyl methacrylate, N-t-butylacrylamide,
N-octylacrylamide, 2-hydroxyethyl acrylate, hydroxypropyl acrylates,
2-hydroxyethyl methacrylate, hydroxypropyl methacrylates, alkylene glycol
(meth)acrylates, styrene, unsaturated sulfonic acids.

10. (twice amended) A soft capsule as claimed in claim 2, wherein the amounts of a), b)
and c) are

- a) 10 to 98% by weight
- b) 2 to 90% by weight
- c) 0 to 50% by weight.

11. (twice amended) A soft capsule as claimed in claim 2, wherein the amounts of a), b)
and c) are

- a) 50 to 97% by weight
- b) 3 to 50% by weight
- c) 0 to 20% by weight.

12. (twice amended) A soft capsule as claimed in claim 2, wherein the amounts of a), b)
and c) are

- a) 65 to 97% by weight
- b) 3 to 35% by weight
- c) 0 to 20% by weight.

13. (twice amended) A soft capsule as claimed in claim 1, wherein the resulting

polymers are subsequently crosslinked.

121 14. (twice amended) A soft capsule as claimed in claim 13, wherein the resulting polymers are subsequently crosslinked by reaction with one or more compounds selected from the group consisting of dialdehydes, diketones, dicarboxylic acids, boric acid, boric acid salts, and salts of multiply charged cations.

15. (twice amended) A soft capsule as claimed in claim 1, wherein the structure-improving auxiliaries (b) employed are compounds from the following classes:

- a) polymers with a molecular weight of more than 50000
- b) substances leading to crosslinking of the polymer chains of the polymers,
- c) and, optionally, substances which lead to crosslinking of the polymer chains of the structure-improving auxiliaries.

16. (twice amended) A soft capsule as claimed in claim 1, wherein the structure-improving auxiliaries employed are polymers selected from the group consisting of the following classes of substances:

polyamino acids, polysaccharides and synthetic polymers

13 2 18. (amended) A soft capsule as claimed in claim 1, which consists of from 10 to 100% by weight of polymers of vinyl esters on polyether, from 0 to 80% of structure-improving auxiliaries and, from 0 to 30% of said other constituents.

19. (amended) A soft capsule as claimed in claim 1, obtained by a process selected from the group consisting of the rotary die process, Accogel process, Norton

process, drop or blow process or the Colton-Upjohn process.

B 2 20. (twice amended) A soft capsule as claimed in claim 1, which comprises one or more active pharmaceutical ingredients, vitamins, carotenoids, minerals, trace elements, food supplements, cosmetic active ingredients, crop protection agents, bath additives, perfume, flavoring, cleaners or detergents.

21. (twice amended) A soft capsule as claimed in claim 1, wherein the capsule comprises from 20 to 80% of a polymer resistant to gastric fluid.

22. (twice amended) A soft capsule as claimed in claim 1, wherein resistance to gastric fluid is achieved by applying after production a coating resistant to gastric fluid by pharmaceutical coating processes.

23. (twice amended) The soft capsule as claimed in claim 20 which comprises one or more pharmaceutical ingredients.

24. (twice amended) The soft capsule as claimed in claim 20 which comprises one or more cosmetic active ingredients, crop protection agents, cleaners or food supplements.

B 3 27. (new) A soft capsule as claimed in claim 16, wherein said polyamino acids are selected from the group consisting of gelatin, zein, soybean protein and derivatives thereof.

28. (new) A soft capsule as claimed in claim 16, wherein said polysaccharides are selected from the group consisting of starch, degraded starch, maltodextrins, carboxymethylstarch, cellulose, hydroxypropylmethylcellulose,

hydroxypropylcellulose, hydroxyethylcellulose, methylcellulose, carboxymethylcellulose, ethylcellulose, cellulose acetate, cellulose acetate phthalate, hydroxypropylcellulose acetate phthalate, hydroxypropylcellulose acetate succinate, hemicellulose, galactomannans, pectins, alginates, carrageenans, xanthan, gellan, dextran, curdlan, pullulan, gum arabic, chitin, and derivatives thereof.

29. (new) A soft capsule as claimed in claim 16, where said synthetic polymers are selected from the group consisting of polyacrylic acid, polymethacrylic acid, copolymers of acrylic esters and methacrylic esters, polyvinyl alcohols, polyvinyl acetate, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones and derivatives thereof.

30. (new) A soft capsule as claimed in claim 1, wherein the amounts of (a), (b) and (c) are:

- (a) 20 to 98% by weight;
 - (b) 1 to 50% by weight; and
 - (c) 0.1 to 30% by weight.
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